



Patent
Attorney's Docket No. 032775-091

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Coffey et al.) Group Art Unit: 1642
Application No.: 10/076,074) Examiner: Unassigned
Filed: February 15, 2002)
For: Sensitization of Chemotherapeutic)
Agent Resistant Neoplastic Cells with)
a Virus)

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

1. U.S. Patent No. 6,136,307
2. U.S. Patent No. 6,100,243
3. WO 94/18992, published September 1, 1994.
4. WO 94/25627, published November 10, 1994.
5. WO 99/18799, published April 22, 1999.
6. Andreansky, S.A., et al., "The application of genetically engineered herpes simplex viruses to the treatment of experimental brain tumors", *Proc. Natl. Acad. Sci.* **93**(21):11313-11318 (1996).

7. Bar-Eli, N., et al., "Preferential cytotoxic effect of Newcastle disease virus on lymphoma cells", *J. Cancer Res. Clin. Oncol.* **122**: 409-415 (1996).
8. Bergmann, M., et al., "A Genetically Engineered Influenza A Virus with *ras*-Dependent Oncolytic Properties", *Cancer Res.* **61**:8188-8193 (2001).
9. Bischoff JR. et al., "An Adenovirus Mutant that Replicates Selectively in p53-Deficient Human Tumor Cells", *Science* **274(5286)**:373-6 (1996).
10. Blagoslelonny, M.V., et al., "*in vitro* Evaluation of a p53-Expressing Adenovirus as an Anti-Cancer Drug", *Int. J. Cancer* **67(3)**:386-392 (1996).
11. Borst et al., "A Family of Drug Transporters: the Multidrug Resistance-Associated Proteins", *J. Natl. Cancer Inst.* **92(16)**: 1295-1302 (2000).
12. Chandran and Nibert, "Protease Cleavage of Reovirus Capsid Protein $\mu 1/\mu 1C$ is Blocked by Alkyl Sulfate Detergents, Yielding a New Type of Infectious Subvirion Particle", *J. of Virology* **72(1)**:467-75 (1998).
13. Chang et al., "Rescue of Vaccinia Virus Lacking the E3L Gene by Mutants of E3L", *J. Virol.* **69**:6605-6608 (1995).
14. Chang et al., "The E3L gene of vaccinia virus encodes an inhibitor of the interferon-induced, double-stranded RNA-dependent protein kinase", *Proc. Natl. Acad. Sci.* **89**:4825-4829 (1992).
15. Chang et al., "Identification of a Conserved Motif that is Necessary for Binding of the Vaccinia Virus E3L Gene Products to Double-Stranded RNA", *Virol.* **194**:537-547 (1993).
16. Coffey, M.C., et al., "Reovirus Therapy of Tumors with Activated Ras Pathway", *Science* **282**: 1332-1334 (1998).
17. DeVita, Jr., "The Relationship Between Tumor Mass and Resistance to Chemotherapy. Implications for Surgical Adjuvant Treatment of Cancer", *Cancer* **51**:1209-1220 (1983).
18. Duncan et al., "Conformational and Functional Analysis of the C-Terminal Globular Head of the Reovirus Cell Attachment Protein", *Virology* **182(2)**:810-9 (1991).

19. Farassati, F., et al., "Oncogenes in Ras signalling pathway dictate host-cell permissiveness to herpes simplex virus 1", *Nat. Cell Biol.* **3(8)**:745-750 (2001).
20. Fueyo, J., et al., "A Mutant Oncolytic Adenovirus Targeting the Rb Pathway Produces Anti-Glioma Effect *in Vivo*", *Oncogene* **19(1)**:2-12 (2000).
21. Grant et al., "Overexpression of Multidrug Resistance-Associated Protein (MRP) Increases Resistance to Natural Product Drugs", *Cancer Res.* **54**: 357-361 (1994).
22. Heise, C. et al., "Replication-selective adenoviruses as oncolytic agents", *J. Clin. Invest.* **105(7)**:847-51 (2000).
23. Kawagishi-Kobayashi, M. et al., "Regulation of the Protein Kinase PKR by the Vaccinia Virus Pseudosubstrate Inhibitor K3L is Dependent on Residues Conserved between the K3L Protein and the PKR Substrate eIF2 α ", *Mol. Cell. Biol.* **17**:4146-4158 (1997).
24. Khuri, et al., "A controlled trial of intratumoral ONYX-015, a selectively-replicating adenovirus, in combination with cisplatin and 5-fluorouracil in patients with recurrent head and neck cancer", *Nat Med* **6(8)**:862-3 (2000).
25. Mah et al., "The N-Terminal Quarter of Reovirus Cell Attachment Protein $\sigma 1$ Possesses Intrinsic Virion-Anchoring Function", *Virology* **179(1)**:95-103 (1990).
26. Nemunaitis, J., "Oncolytic viruses", *Invest. New Drugs* **17**:375-386 (1999).
27. Pastan and Gottesman, "Multidrug Resistance", *Annu. Rev. Med.* **42**: 277-286 (1991).
28. Reichard, K.W., et al., "Newcastle Disease Virus Selectively Kills Human Tumor Cells", *J. of Surgical Research* **52**:448-453 (1992).
29. Romano et al., "Inhibition of Double-Stranded RNA-Dependent Protein Kinase PKR by Vaccinia Virus E3: Role of Complex Formation and hte E3 N-Terminal Domain", *Mol. Cell. Bio.* **18(12)**:7304-7316 (1998).

30. Sharp et al., "The Vaccinia Virus E3L Gene Product Interacts with both the Regulatory and the Substrate Binding Regions of PKR: Implications for PKR Autoregulation", *Virology* **250**:302-315 (1998).
31. Smith, R.E., et al., "Polypeptide Components of Virions, Top Component and Cores of Reovirus Type 3", *Virology*, **39**:791-800 (1969).
32. Stojdl, D.F., et al., "Exploiting tumor-specific defects in the interferon pathway with a previously unknown oncolytic virus", *Nat. Med.* **6(7)**:821-825 (2000).
33. Strong, J.E., et al., "The molecular basis of viral oncolysis: usurpation of the Ras signaling pathway by reovirus", *EMBO J.* **17**: 3351-3362 (1998).
34. Turner and Duncan, "Site-Directed Mutagenesis of the C-terminal Portion of Reovirus Protein $\sigma 1$: Evidence for a Conformation-Dependent Receptor Binding Domain", *Virology* **186(1)**:219-27 (1992).
35. Yoon, S.S., et al., "An oncolytic herpes simplex virus type I selectively destroys diffuse liver metastases from colon carcinoma", *FASEB J.* **14**:301-311(2000).
36. Zorn, U. et al., "Induction of Cytokines and Cytotoxicity against Tumor Cells by Newcastle Disease Virus", *Cancer Biotherapy* **9(3)**:22-235 (1994).

These documents are being submitted within three months from the filing date of the present application. Consequently, no fee is required pursuant to 37 C.F.R. §1.97(b).


By citing the above references, Applicants do not acquiesce or admit that any of these documents are "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449.
It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____


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Date: May 9, 2002



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Coffey et al.

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**INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

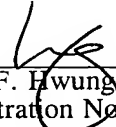
- ☒ [X] No additional fee for submission of an IDS is required.
- ☐ [] The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ [] A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ [] A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ [] Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- ☐ [] A check in the amount of \$_____ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

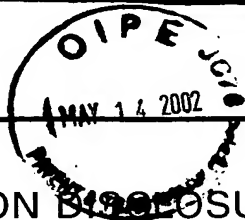
Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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U.S. PATENT DOCUMENTS

Examiner Initials	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication (MM-DD-YYYY)
	Number	Kind Code (if known)		
	6,136,307		Lee et al.	10-24-2000
	6,100,243		Frisch	08-08-2000

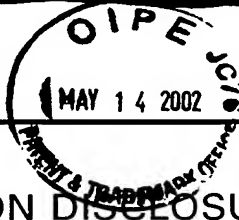
FOREIGN PATENT DOCUMENTS

Examiner Initials	Foreign Patent Document		Country	Date of Publication (MM-DD-YYYY)	Translation	
	Number	Kind Code (if known)			Yes	no
	WO 94/18992		PCT	09-01-1994		
	WO 94/25627		PCT	11-10-1994		
	WO 99/18799		PCT	04-22-1999		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Andreansky, S.A., et al., "The application of genetically engineered herpes simplex viruses to the treatment of experimental brain tumors", <i>Proc. Natl. Acad. Sci.</i> 93(21):11313-11318 (1996).
	Bar-Eli, N., et al., "Preferential cytotoxic effect of Newcastle disease virus on lymphoma cells", <i>J. Cancer Res. Clin. Oncol.</i> 122: 409-415 (1996).
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.



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